CLAIMS

What is claimed is:

add a2

1. An adenovirus vector comprising an adenovirus gene under transcriptional control of an α fetoprotein transcription regulatory element (AFP-TRE).

2. The adenovirus vector of claim 1, wherein the adenovirus gene is essential for viral replication.

3. The adenovirus vector of claim 2, wherein the adenovirus gene is an early gene.

4. The adenovirus vector of claim 2, wherein the adenovirus gene is a late gene.

5. The adenovirus vector of claim 3, wherein the adenovirus early gene is E1A.

6. The adenovirus vector of claim 3, wherein the adenovirus early gene is E1B.

7. The adenovirus vector of claim 3, wherein the adenovirus early gene is E4.

8. The adenovirus vector of claim 1, wherein the adenovirus gene is the adenovirus death protein gene (ADP).

9. The adenovirus vector of claim 1, wherein the AFP-TRE comprises an enhancer from an AFP gene.

10. The adenovirus vector of claim 9, wherein the enhancer comprises nucleotides from about 1 to about 300 of SEQ ID NO:1.

11. The adenovirus vector of claim 9, wherein the AFP-TRE comprises nucleotides from about 300 to about 600 of SEQ ID NO:1.

12. The adenovirus vector of claim 9, wherein the AFP-TRE comprises nucleotides from about 1 to about 600 of SEQ ID NO:1.

13. The adenovirus vector of claim 1, wherein the AFP-TRE comprises a promoter from a AFP gene.

14. The adenovirus vector of claim 13, wherein the AFP-TRE comprises nucleotides from about 600 to about 827 of SEQ ID NO:1.

15. The adenovirus vector of claim 1, wherein the AFP-TRE comprises an AFP promoter and an AFP enhancer.

16. The adenovirus vector of claim 15, wherein the AFP-TRE comprises SEQ ID NO:1.

17. The adenovirus vector of claim 15, wherein the AFP-TRE comprises SEQ ID NO:2.

18. A composition comprising an adenovirus of claim 1.

19. The composition of claim 18, further comprising a pharmaceutically acceptable excipient.

20. The adenovirus vector of claim 1, further comprising at least one additional adenovirus gene under transcriptional control of a second AFP-TRE.

21. The adenovirus vector of claim 20, wherein the genes under transcriptional control of AFP-TREs are both early genes.

22. The adenovirus vector of claim 21, wherein the genes under transcriptional control of AFP-TREs are E1A and E1B.

23. The adenovirus vector of claim 20, further comprising an additional adenovirus gene under transcriptional control of a third AFP-TRE.

24. The adenovirus vector of claim 23, wherein the adenovirus genes under transcriptional control are E1A, E1B, and E4.

25. A composition comprising an adenovirus of claim 21.

26. The composition of claim 25, further comprising a pharmaceutically acceptable excipient.

27. A non-naturally occurring adenoviral vector comprising a polynucleotide encoding an adenovirus death protein (ADP) polypeptide.

28. The adenoviral vector of claim 27, wherein the ADP polypeptide is a sequence depicted in SEQ ID NO:23.

29. The adenoviral vector of claim 27, wherein the ADP polypeptide is SEQ ID NO:23.

30. The adenoviral vector of claim 27, wherein the polynucleotide is contained within SEQ ID NO:22.

31. The adenoviral vector of claim 27, wherein the polynucleotide is SEQ ID NO:22.

32. The adenoviral vector of claim 27, wherein the polynucleotide encoding ADP is under transcriptional control of a cell-specific transcriptional regulatory element.

33. The adenoviral vector of claim 32, wherein the cell-specific transcriptional element is prostate-cell specific.

34. The adenoviral vector of claim 33, wherein the prostate-cell specific TRE is from prostate specific antigen gene, human kallikrien gene, or probasin gene.

35. The adenoviral vector of claim 32, wherein the cell-specific transcriptional element is an AFP-TRE.

36. A host cell comprising the adenoviral vector of claim 1.

37. A host cell comprising the adenoviral vector of claim 20.

38. A host cell comprising the adenoviral vector of claim 24.

39. A host cell comprising the adenoviral vector of claim 27.

40. A method of propagating adenovirus specific for cells which allow an AFP-TRE to function, said method comprising combining an adenovirus according

to claim 1 with cells which allow an AFP-TRE to function, whereby said adenovirus is propagated.

41. A method of propagating adenovirus specific for cells which allow an AFP-TRE to function, said method comprising combining an adenovirus according to claim 20 with cells which allow an AFP-TRE to function, whereby said adenovirus is propagated.

42. A method for modifying the genotype of a target cell, said method comprising contacting a cell with an adenoviral vector of claim 1 to allow entry of the vector into the cell.

43. A method for modifying the genotype of a target cell, said method comprising contacting a cell with an adenoviral vector of claim 20 to allow entry of the vector into the cell.

44. A method for conferring selective cytotoxicity on a target cell, said method comprising contacting a cell which allows an AFP-TRE to function with an adenovirus vector of claim 1, whereby the vector enters the cell.

45. A method for conferring selective cytotoxicity on a target cell, said method comprising contacting a cell which allows an AFP-TRE to function with an adenovirus vector of claim 20, whereby the vector enters the cell.

46. A method of detecting cells which allow an AFP-TRE to function a biological sample comprising the steps of:

contacting a biological sample with an adenovirus vector of claim 1, under conditions suitable for AFP-TRE-mediated gene expression in the cells; and

determining if AFP-TRE mediates gene expression in the biological sample,

wherein AFP-TRE-mediated gene expression indicates the presence of cells which allow an AFP-TRE to function.

47. A method of suppressing tumor growth in an individual having an AFP-expressing tumor, comprising contacting tumor cells with the adenoviral vector

of claim 2, wherein the adenoviral vector transfects the tumor cells and replicates.

48. A method of treating cancer in an individual having an AFP-producing tumor, comprising administering to the individual an effective amount of an adenovirus vector of claim 2.

49. An adenovirus comprising an adenoviral vector of claim 1, wherein the adenovirus is complexed with a masking agent.

50. The adenovirus of claim 49 wherein the masking agent is polyethyleneglycol (PEG).

51. The adenovirus of claim 50, wherein the PEG is of a molecular weight between about 2500 to about 30,000.

52. The adenovirus of claim 51, wherein the PEG is of a molecular weight between about 3000 to about 20,000.

53. The adenovirus of claim 52, wherein the PEG is of a molecular weight between about 5000 to about 10,000.

54. The adenovirus of claim 50, wherein the PEG is covalently attached to the adenovirus.

55. The adenovirus of claim 50, wherein the PEG is non-covalently attached to the adenovirus.

56. The adenovirus of claim 54, wherein the PEG is covalently attached by using a N-hydroxysuccinimidyl (NHS) active ester.

57. The adenovirus of claim 56, wherein the N-hydroxysuccinimidyl (NHS) active ester is selected from the group consisting of succinimidyl succinate, succinimidyl succinamide and succinimidyl propionate.

58. The adenovirus of claim 57, wherein the N-hydroxysuccinimidyl (NHS) active ester is succinimidyl succinate.

59. A method of making a masked adenovirus , comprising covalently attaching a masking agent to an adenovirus, wherein the masking agent is has a molecular weight between about 2500 and about 20,000, thereby producing a masked adenovirus.

60. The method of claim 59, wherein the masking agent is polyethyleneglycol (PEG).

61. An adenovirus complexed with a masking agent.

62. The adenovirus of claim 61 wherein the masking agent is polyethyleneglycol (PEG).

63. The adenovirus of claim 62, wherein the PEG is of a molecular weight between about 2500 to about 30,000.

64. The adenovirus of claim 63, wherein the PEG is of a molecular weight between about 3000 to about 20,000.

65. The adenovirus of claim 64, wherein the PEG is of a molecular weight between about 5000 to about 10,000.

66. The adenovirus of claim 62, wherein the PEG is covalently attached to the adenovirus.

67. The adenovirus of claim 62, wherein the PEG is non-covalently attached to the adenovirus.

68. The adenovirus of claim 66, wherein the PEG is covalently attached by using a N-hydroxysuccinimidyl (NHS) active ester.

69. The adenovirus of claim 68, wherein the N-hydroxysuccinimidyl (NHS) active ester is selected from the group consisting of succinimidyl succinate, succinimidyl succinamide and succinimidyl propionate.

70. The adenovirus of claim 69, wherein the N-hydroxysuccinimidyl (NHS) active ester is succinimidyl succinate.